VOL 05 510(k) Summary

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR §807.92.

The assigned 510(k) number is: K131243

NOV 1 2 2013

1.0 Information of Submitter and Correspondent

Submitter's Information:

Shenzhen Jumper Medical Equipment Co., Ltd.
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Contact Person: Mr. Yi Hui
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Submission correspondent's information:

Shenzhen ZYTC Consulting Co., Ltd.
Address: 4th Floor, Jinhui Building, Nanhai BLVD, Nanshan District, Shenzhen, Guangdong, China.
Contact person: Mr. Field.Fu E-mail: cefda13485@163.com

2.0 Device Information

Type of 510(k) submission:	Traditional
Trade Name:	Non-contact Infrared Thermometer
Model:	JPD-FR100
Classification name:	thermometer, electronic, clinical
Review Panel:	General Hospital
Product Code:	FLL
Device Class:	II
Regulation Number:	880.2910

3.0 Predicate Device Information

Sponsor: K-jump Health Co., Ltd.
Device: Non-contact Infrared Thermometer, model KI-8280
510(K) Number: K102947

4.0 Device Description

The Non-contact Infrared Thermometer, Model JPD-FR100, uses infrared sensor (thermopile) to detect the radiated infrared energy emitted by the object, solid, liquid or gas. The intensity of the emitted energy depends on the temperature of the object and the infrared sensor can recognize it to transfer to the proper electronic signal. The electronic signal can be processed in the subject device to convert to the temperature reading. Therefore, the subject device is able to measure the temperature of a person by the energy the person emits. The predicated device KI-8280, use the same detection principle to measure the patient's temperature.

The subject device also use the focusing design to collect the infrared emitted from nearby area of patient's forehead. This mechanism make the subject device have the ability to detect the forehead temperature in the distance of 1-6cm. The subject device intended to detect the temperature of patients. The temperature is converted to the oral temperature. The temperature reading shown in the device display after measuring is the patient's oral temperature.

The compact, small and light-weight design, the Shenzhen Jumper Medical Equipment Co., Ltd. Non-contact Infrared Thermometer, model JPD-FR100, enables to provide safe and reliable result and offers a very good clinical accuracy for human body temperature measurements.

5.0 Intended Use

The non-contact infrared thermometer, model JPD-FR100, can measure body temperature for infants and adults without contact to human body. It can be used by consumers in household environment and doctor in clinic as reference.

6.0 Performance Summary

Non-contact Infrared Thermometer, model JPD-FR100 was conforms to the following standards:

- IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988+A1:1991+A2:1995
- IEC 60601-1-2, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests, 2007
- IEC 60601-1-11:2010, Medical electrical equipment – General requirements for basic safety and essential performance - Part 1-11: Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.
- ASTM E1965-98 (2009), Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature.
- IEC 62304:2006, Medical device software – Software life cycle processes.
- ISO 10993-1, Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process, 2009
- ISO 10993-5, Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity, 2009
- ISO 10993-10:2010, Biological evaluation of medical devices – Part 10: Tests for irritation and delayed-type hypersensitivity
- ISO 14971:2007, Medical devices – Application of risk management to medical devices.

7.0 Comparison to predicate device and conclusion

The subject device is substantially equivalent to predicate devices, K102947, KI-8280. The substantial equivalence chart is provided as follows:

Characteristics	Subject Device	Predicate Device
Device name	Non-contact Infrared Thermometer	Non-contact Infrared Thermometer
Model	JPD-FR100	KI-8280
K number	Pending	K102947
Manufacturer	Shenzhen Jumper Medical Equipment Co., Ltd.	K-jump Health Co., Ltd.
Measurement method	Infrared radiation detection	Infrared radiation detection

Measurement mode	Forehead measure mode	Forehead and surface measure mode
Measuring range	Forehead temperature mode: 32.2℃-43.3℃(90.0℉-109.9℉);	Forehead temperature mode: 32.0℃-42.2℃(89.6℉-107.9℉); Surface temperature mode: 0.0℃-100℃(32℉-212℉);
Display resolution	0.1℃(0.1℉)	0.1℃(0.1℉)
C/F switchable	Yes	Yes
Measuring accuracy	Forehead temperature mode: ±0.2℃(0.4℉);	Forehead temperature mode: ±0.2℃(0.4℉); Surface temperature mode: ±1℃(1.8℉)
Display	LCD display	LCD display
Measurement distance	1-6cm	3-8cm
Key	Two button (Forehead measure, temperature unit shift)	Two button (On/off, Memory)
Memory	20 sets	10 sets
Power source	Two 1.5V AAA batteries	Two 1.5V AAA batteries
Low battery indication	Yes	Yes
Waterproof	No	No
Dimension	145×60×50mm	138×90×45mm
Weight	180g	125g(including batteries)
Operating condition	10℃-40℃(50℉-104℉), < 95%RH, no-condensing	10℃-40℃(50℉-104℉), < 95%RH, no-condensing

8.0 Clinical Tests Performed

The clinical performance test protocol and data analysis followed the requirements of ASTM E 1965. The test report showed the clinical performance of subject device complied with the requirements of ASTM E1965. It is acceptable to measure patient's temperature.

9.0 Conclusions

Non-contact Infrared Thermometer, Model JPD-FR100, has the same intended use and similar characteristics as the predicate device. Moreover, the subject device demonstrates product safety by successful completion of testing to the IEC 60601-1 standard and

electromagnetic standard IEC 60601-1-2. The performance test demonstrates the JPD-FR100 meets the ASTM E 1965 and concludes that any differences in their characteristics do not raise any safety and effectiveness issues.

From the above information we conclude the subject device, JPD-FR100, is substantially equivalent to the predicate devices, KI-8280.

10.0 Summary prepared date

November 11, 2013

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 12, 2013

Shenzhen Jumper Medical Equipment Company, Limited
C/O Mr. Field Fu
Shenzhen ZYTC Consulting Company, Limited
4th Floor, Jinhui Building, Nanhai Boulevard
Nanshen District, Shenzhen, Guandong
CHINA 518052

Re: K131243
Trade/Device Name: Non-contact Infrared Thermometer, Model JPD-FR100
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: October 10, 2013
Received: November 5, 2013

Dear Mr. Fu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

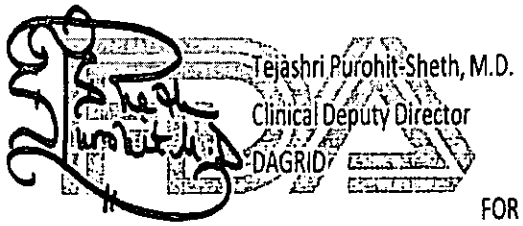
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



FOR

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K131243

Device Name
Non-contact Infrared Thermometer, Model JPD-FR100

Indications for Use *(Describe)*
Non-contact Infrared Thermometer, model JPD-FR100, can measure body temperature for infants and adults without contact to human body. It can be used by consumers in household environment and doctor in clinic as reference.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

FDA

Richard C. Chapman
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